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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,596	02/18/2004	Robert Falotico	CRD-5065	3367

27777 7590 01/07/2009  
PHILIP S. JOHNSON  
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ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
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PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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01/07/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/780,596	<b>Applicant(s)</b> FALOTICO ET AL.	
	<b>Examiner</b> Brian E. Pellegrino	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's AF submission filed on 9/4/08 has been entered.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robida (2005/166841). Figs. 2,3 show a stent. Robida also discloses (paragraph 54) other medical devices, such as stent grafts and devices capable of being an anastomosis device. Robida discloses that the device is to be coated with drugs and can include combinations of rapamycin and cladribine, paragraphs 56,61. Robida additionally discloses the therapeutic agents are combined in a polymer material, paragraph 62. Robida discloses the polymer can be an acrylic, paragraphs 62,63. Robida also discloses that the device can be coated with multiple layers and have different polymers, paragraph 67. However, Robida does not explicitly disclose the concentration of cladribine having a range of about 56 nano-molar to 900 nano-molar. It

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would have been obvious to one of ordinary skill in the art at the time the invention was made to use cladribine with a concentration within the range between about 56 nano-molar to 900 nano-molar, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopia et al. (WO 01/87372) in view of Morris et al. (5516781). Kopia et al. disclose a stent coated with a polymer having a combination of drugs, including rapamycin and another drug, page 7, lines 14-17,22-30. Kopia does disclose multiple antiproliferative drugs, such as rapamycin and cladribine, page 7, line 17. Table 2 illustrates the stent has a basecoat and a topcoat. The device could be construed as a stent-graft since it includes coatings. The device also could function as an anastomosis implant. Please note the intended use carries no weight in the absence of any distinguishing structure. However, Kopia does not explicitly disclose the combination of rapamycin and cladribine or the concentration of cladribine having a range of about 56 nano-molar to 900 nano-molar. Morris et al. teach that rapamycin can be combined with other antiproliferative drugs to treat vascular disease, col. 4, lines 10-22. It would have been obvious to one of ordinary skill in the art to combine antiproliferative agents as taught by Morris et al. and use the two antiproliferatives combined such as cladribine and rapamycin on the stent of Kopia to obtain a synergistic effect to reduce or prevent restenosis. Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use cladribine with a concentration within the range between about 56 nano-

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molar to 900 nano-molar, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 6,7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopia et al. (WO 01/87372) in view of Morris et al. '781 as applied to claim 1 above, and further in view of Ragheb et al. (2003/36794). Kopia '372 as modified by Morris '781 is explained above. However, Kopia in view of Morris fail to disclose the polymers used for the coating as fluoropolymers and acrylics. Ragheb et al. teach the use of acrylic polymers (paragraphs 74-76) and fluoropolymers (paragraphs 22,53,115) with a rapamycin stent, paragraphs 17,63,65. It would have been obvious to one of ordinary skill in the art to substitute polymers and utilize fluoropolymers and acrylics as taught by Ragheb et al. with the stent of Kopia '372 as modified by Morris '781 such that it provides inert coatings that are separate and distinct in order to provide different release rates.

### ***Response to Arguments***

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the amended claims patentably distinguishes them from the references. Clearly someone of ordinary skill in the art has the capability of finding the optimal amount of a drug to be used in a patient and in this instance the skill is high being because the person of skill is a surgeon or doctor. Finding the right or appropriate amount to administer to a patient only involves routine skill. Thus, the prior

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art references disclose the claimed invention alone or in combination as discussed above and it is obvious to one of ordinary skill in the art to find the optimal concentration of a drug to deliver to a patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700  
/Brian E Pellegrino/  
Primary Examiner, Art Unit 3738